K011994

NOV 0 8 2001

510(k) Summary

Contact Person: Dr. Bruce L. Gibbins, Chairman & CTO

Date of preparation: June 22, 2001

Device Name (proprietary): AcryDerm Silver Antimicrobial Wound Gel

Common Name: Moist antimicrobial wound filler

Classification Name: Amorphous Hydrogel Wound Dressing

Classification: Unclassified

Legally marketed device(s) for substantial equivalence comparison:

AcryDerm Silver Antimicrobial Wound Dressing (AcryMed, Inc., OR)
AcryDerm Gel Wound Dressing (AcryMed, Inc., OR)

Description of Device: AcryDerm Silver Antimicrobial Wound Gel is a line extension of the previously cleared product, AcryDerm Gel Wound Dressing. The new product is a moist amorphous gel wound filler that contains antimicrobial silver that inhibits the growth of microbial contaminants in contact with the dressing. The high moisture content gel contains a base matrix composed of hydrophilic polyacrylate absorbent microspheres that contain a silver complex and stabilizers to prevent discoloration and staining from the dressing. AcryDerm Silver Antimicrobial Wound Gel will be supplied in collapsible blind ended heat sealed co-laminate foil tubes fitted with screw caps. The reusable product primaries will be packed in individual dispenser boxes with a product insert. Biocompatibility has been assessed according to Part-1 of the ISO standard (*Biological Evaluation of Medical Devices*).

Intended Use of the Device: AcryDerm Silver Antimicrobial Wound Gel is an amorphous wound moisture management gel that is an effective antimicrobial barrier. The antimicrobial barrier function of the dressing may help reduce infection in partial and full thickness wounds including decubitus ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, abrasions and lacerations, donor sites and surgical wounds. AcryDerm Silver may be used over debrided and grafted partial thickness wounds.

Technological Characteristics: AcryDerm Silver Antimicrobial Wound Gel is an amorphous gel wound filler that controls wound moisture levels through dual function of donation and absorption. Antimicrobial action is conferred by its content of stabilized antimicrobial silver. The product carries the general classification name, "Amorphous hydrogel wound dressing". The composition of AcryDerm Silver Antimicrobial Wound Gel is identical to the predicate device, AcryDerm Gel Wound Dressing except that its preservatives have been replaced by silver technology which is in the predicate, AcryDerm Silver Antimicrobial Wound Dressing. AcryDerm Silver Antimicrobial Wound Gel contains silver that may control microbial contamination of the dressing.

Manufacturing: AcryDerm Silver Antimicrobial Wound Gel will be manufactured according to the product specifications and under good manufacturing practices that ensure the device is safe and effective antimicrobial barrier.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 8 2001

Bruce Gibbins, Ph.D
Chief Technical Officer
AcryMed, Inc.
12232 SW Garden Place
Portland, Oregon 97223

Re: K011994
Trade/Device Name: AcryDerm Silver Antimicrobial Wound Gel
Regulatory Class: Unclassified
Product Code: MGQ
Dated: August 28, 2001
Received: August 29, 2001

Dear Dr. Gibbins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 0 8 2001

510(k) NUMBER (IF KNOWN): K011994

DEVICE NAME: **AcryDerm Silver Antimicrobial Wound Gel**

INDICATIONS FOR USE:

AcryDerm Silver Antimicrobial Wound Gel is an amorphous wound moisture management gel that is an effective antimicrobial barrier. The antimicrobial barrier function of the dressing may help control bioburden and reduce the incidence of infection in partial and full thickness wounds including decubitus ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, abrasions and lacerations, donor sites and surgical wounds. AcryDerm Silver may be used over debrided and grafted partial thickness wounds.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use X OR Over-The-Counter-Use
(Per 21 CFR 801.109) (Optional Format 1)

Susan Walker
(Division Sign-Off)
Division of General, Restorative and Neurological Devices